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# Congress of the United States

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December 22, 2003

Mark B. McClellan, M.D., Ph.D.  
Commissioner  
U. S. Food and Drug Administration  
5600 Fishers Lane  
Rockville MD 20857-0001

Dear Dr. McClellan,

I invite you to testify before the Subcommittee on Criminal Justice, Drug Policy and Human Resources on Wednesday, January 28, 2004 at 10 a.m. in 2154 Rayburn House Office Building regarding the status of federal efforts related to cervical cancer and human papillomavirus (HPV).

Public Law 106-554 directs the Food and Drug Administration to "reexamine existing condoms labels... to determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness in preventing sexually transmitted diseases, including HPV." It now has been three years since this law by signed by President Clinton and FDA has not yet complied with this directive.

HPV poses a significant risk to the health of countless Americans, especially women. As you know, infection with high risk strains of HPV is associated with nearly all cervical cancer. About 20 million Americans are currently infected with HPV and an estimated 5.5 million Americans become infected with HPV every year. An estimated 13,000 new cases of invasive cervical cancer are diagnosed annually and over 4,000 women die of the disease every year in the United States. Tens of thousands of others will be treated for HPV related pre-cancerous conditions.

As you know, studies have found conclusive scientific evidence that condoms do not provide effective protection against HPV infection.

A 2001 report entitled "Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention" prepared by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health in consultation with

the FDA, the Centers for Disease Control and Prevention and the U.S. Agency for International Development evaluated the published data on latex condoms and STD prevention and “concluded that there was no evidence that condom use reduced the risk of HPV infection.”

In a 1999 letter to the House Commerce Committee, Dr. Richard D. Klausner, then-Director of the National Cancer Institute (NCI), conceded “condoms are ineffective against HPV.” The science in this regard is so clear that Dr. Klausner concluded “additional research efforts by NCI on the effectiveness of condoms in preventing HPV transmission are not warranted.” Dr. Douglas Lowy, Deputy Director of NCI’s Division of Basic Sciences, explained that “the NCI conclusion that condoms are ineffective against HPV infection is based on the results of several long term studies that have failed to show that barrier contraceptives prevent cervical HPV infection, dysplasia, or cancer.”

And according to the American Cancer Society, “research shows that condoms cannot protect against infection with HPV. This is because HPV can be passed from person to person with any skin-to-skin contact with any HPV-infected area of the body, such as skin of the genital or anal area not covered by the condom. The absence of visible warts cannot be used to decide whether caution is warranted, since HPV can be passed on to another person even when there are no visible warts or other symptoms. HPV can be present for years with no symptoms.”

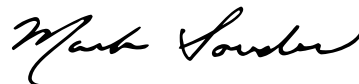
With January designated as Cervical Cancer Awareness Month, it is critically important that FDA inform consumers that condom do not provide effective protection against infection with the virus that can cause cervical cancer as required by law.

I invite you to present the status of FDA efforts to comply with this law before the Subcommittee on January 28. Witnesses will be afforded an opportunity to testify for five minutes. Your written statement for the record may be of any length.

In accordance with Subcommittee procedure, please e-mail your testimony to [Nicole.Garrett@mail.house.gov](mailto:Nicole.Garrett@mail.house.gov) and provide one hundred (100) copies of your prepared statement by close of business Tuesday, January 27.

Thank you for your contribution to this important Congressional hearing. We look forward to your valuable insights. If you have any questions, please contact me or Roland Foster of my staff at (202) 225-2577.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Souder", written in a cursive style.

Mark E. Souder

Chairman

Subcommittee on Criminal Justice,  
Drug Policy and Human Resources